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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,527	12/27/2001	Raymond L. Houghton	210121.513C1	7914

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EXAMINER	
WILDER, CYNTHIA B	

ART UNIT	PAPER NUMBER
1637	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/033,527	HOUGHTON ET AL.	
	Examiner	Art Unit	
	CYNTHIA B. WILDER	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37 and 40-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37 and 41* is/are rejected.

7)☐ Claim(s) *40 and 44-46* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 3/14/2008 is acknowledged and has been entered. Claims 1-36, 38-39, 42-43 have been canceled. Claims 37, 40-41 and 44-46 are pending. All of the arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons discussed below. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims.

This action is made FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Previous Rejection

3. The prior art rejection under 35 USC 103(a) direct to claims 37 and 41 is maintained and discussed below. The prior art rejection directed to claims 44-46 is withdrawn in view of Applicant's arguments at pages 7-9 of Applicant's response.

Claim Rejections - 35 USC § 103

4. Claims 37 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frudakis et al (reference made of record in prior Office action) in view of Weaver et al (citation made of record in the prior art). Regarding claims 37 and 41, Frudakis et al teach a composition for detecting a breast cancer cell in a biological sample of a patient, said composition comprising (a) a first oligonucleotide, (b) a second oligonucleotide, wherein said first oligonucleotide and said second oligonucleotide hybridize to a first polynucleotide, or the complement thereof and to a second polynucleotide or the complement thereof, respectively, wherein said first polynucleotide and said second polynucleotide comprise a sequence depicted in SEQ ID NO: 7 (see SEQ ID NO: 303, col. 9, lines 26-29; col. 14, 18-24 and 40-62; and col. 21, lines 27-50). Frudakis et al teach wherein the composition may have more than one oligonucleotide pair (col. 14).

Frudakis et al does not teach wherein the composition comprises an oligonucleotide or oligonucleotide pair that hybridizes to the sequence of SEQ ID NO: 75 or the complement thereof.

Weaver teaches a composition for detecting breast cancer cells in a biological sample, said composition comprising (a) a first oligonucleotide (b) a second oligonucleotide; wherein said first and second oligonucleotide hybridize to a first polynucleotide, or the complement thereof, and to a second polynucleotide or the complement thereof respectively, wherein said first and second polynucleotide comprise a sequence depicted in SEQ ID NO: 75 (See SEQ ID NO: 1034, paragraphs 0053, 0073, 0081, 0082, and 0090). Weaver et al teaches wherein the sequence recited therein are genes that are up-regulated in cancer cells relative to normal cells. Weaver et al teach that the gene pattern resulting from these genes, such as those encompassing the sequence depicted in SEQ ID NO: 75 (SEQ ID NO: 1034)

are indicative of a cancerous state and thus have potential for development of antitumor agents (see 0081 and 0082).

In view of the foregoing, one of ordinary skill in the art at the time of the claimed invention would have been motivated to have provided a composition comprising oligonucleotides which hybridizes to a sequence comprising the sequence of SEQ ID NO: 7 and 75 for the benefit of providing gene patterns indicative of a cancerous state in biological sample and for the benefit of developing potential antitumor agents as suggested by Weaver et al.

Response to Arguments

5. Applicant traverses the rejection on the following grounds: Applicant states that the primary reference of Frudakis does not teach detection of breast cancer or hybridization to a first and second polynucleotide. Applicant asserts that Frudakis et al teach hybridization and detection of a single sequence at a time, not multiple oligonucleotides simultaneously. Applicant asserts that Frudakis et al do not teach a polynucleotide comprising SEQ ID NO: 75 or in combination to the polynucleotide sequence of SEQ ID NO: 7. Applicant argues that Weaver do not teach the polynucleotide of SEQ ID NO: 7, it's breast cancer expression pattern, nor that compositions comprising oligonucleotides to detect this sequence in combination with the polynucleotide sequence of SEQ ID NO: 75 or any other marker, can be used to better detect breast cancer. Applicant asserts that there is no indication in Frudakis et al or Weaver that these cancer associated markers complement one another and provide expanded cancer detection when used together. Applicant states that nothing in the prior art would have reasonably permitted the person having ordinary skill to predict that the combination of the individual recited cancer-associated markers would provide the advantages of the presently claimed method.

6. All of the arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons that follow: In response to Applicant that Frudakis et

al does not teach detection of breast cancer cells the examiner respectfully disagree because the whole objective of the patent of Frudakis et al is based on compositions and methods for detection and identification of breast cancer genes and cells (see title, abstract, specification and claims). With regards to the composition be capable of hybridizing to a first and second polynucleotide, the Examiner maintains that Frudakis et al meets this limitation as Frudakis et al teach wherein multiple oligonucleotides are designed which specifically hybridizes to B15AG-1, B31GA1b, B38GA2a, B11A1a and B18AG1a). In regards to Applicant's arguments that the reference does not teach hybridization/detection to multiple oligonucleotides sequences simultaneously, it is noted that the claims do not require multiple hybridization or multiple detection simultaneously. Rather, the claims are only require that the one oligonucleotide be capable of hybridizing to a first nucleic acid sequence and the other oligonucleotide be capable of hybridizing to a second nucleic acid sequence. Applicant is reminded that the claims are not drawn to a "method" but rather a "product'. Further, it is noted that the claims do not required "simultaneous" hybridization. MPEP states although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

With regards to Applicants arguments that the reference of Frudakis does not teach a polynucleotide which hybridizes to SEQ ID NO: 75 in combination with SEQ ID NO: 7, it is noted that the secondary reference of Weaver is cited for a teaching of an oligonucleotide capable of hybridizing to a polynucleotide comprising SEQ ID NO: 75.